



Data on Accidental Ingestions

With Focus on
Pediatric Ingestions

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DISCLAIMER

The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee.

Background

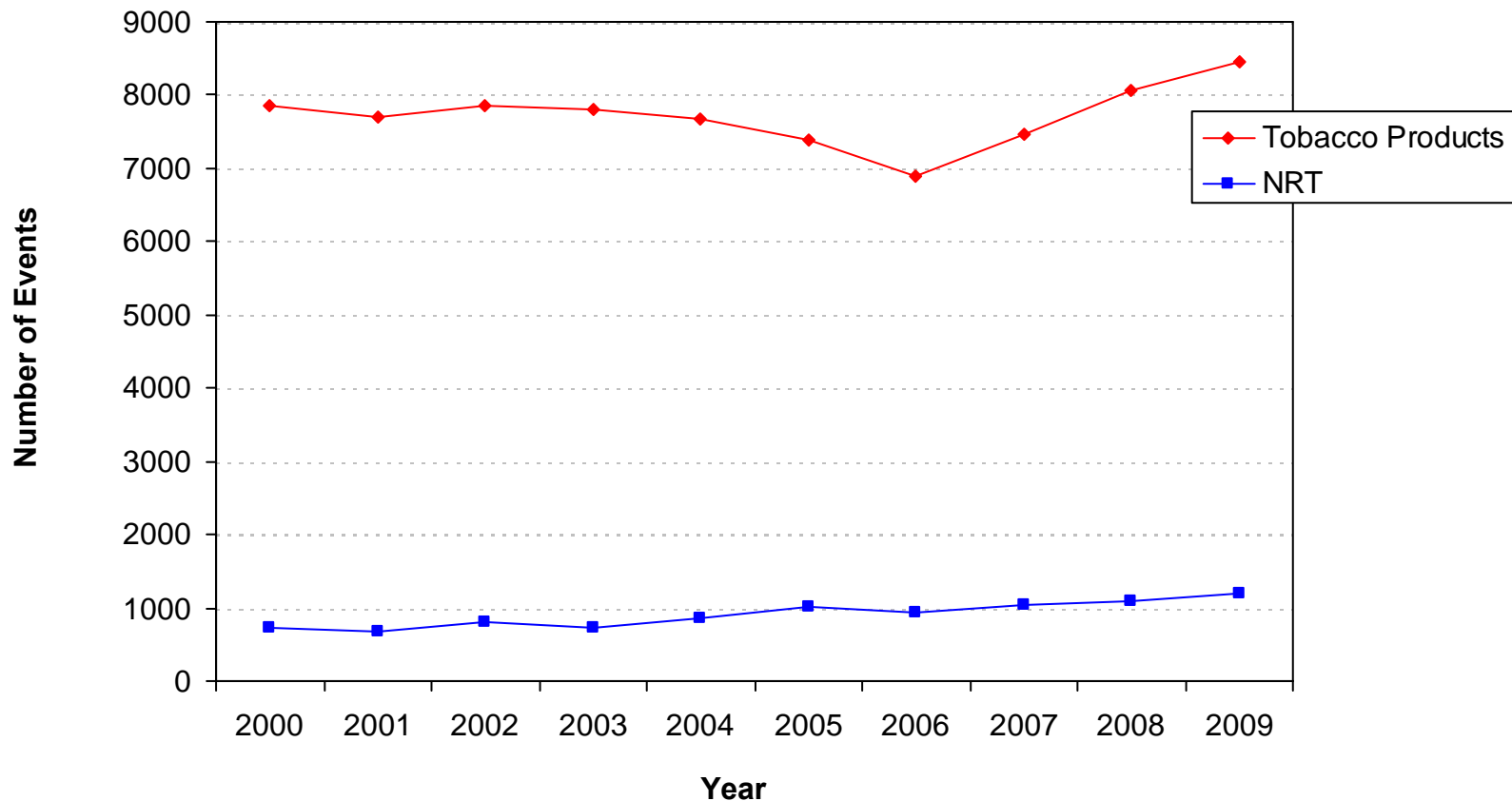
- There has been concern by public health advocates that dissolvable tobacco products may be more appealing to youth in appearance and flavoring compared to traditional cigarettes or smokeless products which in turn may lead to increases in harmful accidental ingestions
- It is estimated that 1 mg/kg body weight of nicotine may be lethal for the pediatric age group; a small handful of dissolvable tobacco product could have the potential for serious consequences in young children

Source of Data

- Derived from American Association of Poison Control Centers (AAPCC)
- Non-profit, national organization representing the poison centers and poison-related organizations in the US
- Owns and maintains the National Poison Data System
- More than 50 million case records covering a 27 year period

Total number of Exposure Events (All Ages) Associated with Tobacco Products and NRT*

Approximately 8,000 tobacco product reports/year and the number of reports appear to be increasing over the recent years



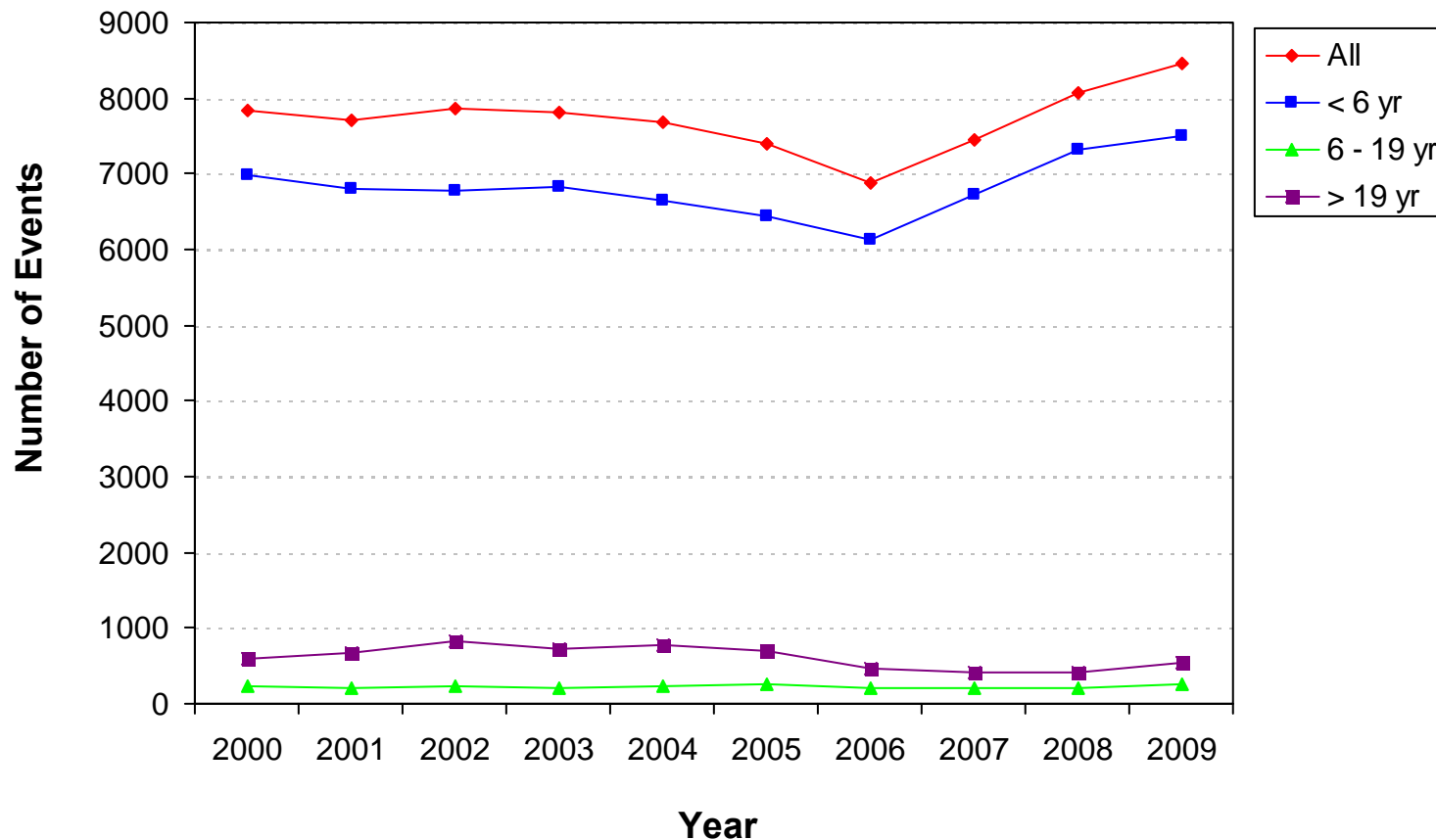
*NRT = Nicotine Replacement Therapies

Policy Change in 2006

- In 2006, AAPCC restricted reporting to single substance cases to improve precision and avoid misinterpretation
- Alcohol tends to be associated with smoking and drug use, this change in reporting policy may have resulted in this difference between reports of single exposure and reports of multiple exposures between 2005 and 2006
- Since 2006, there appears to be a steady increase in number of reported poisoning events more apparent for tobacco products but also appears to be a slight increase for NRT

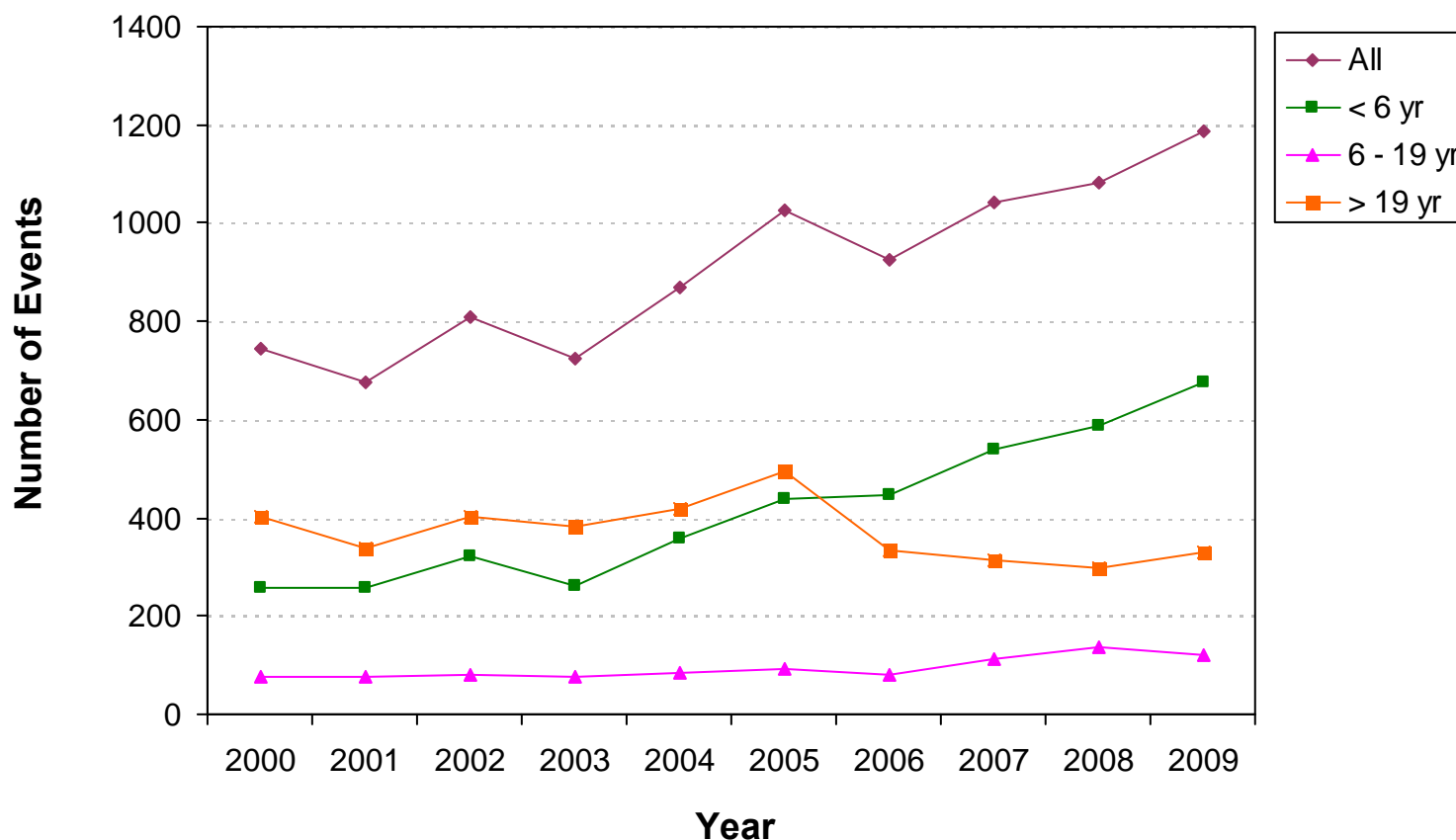
Total number of Tobacco Product-Associated Exposure Events by Age (2000 – 2009)

Vast majority of tobacco reports involve young children; the recent increased number of reports reflect those involving young children



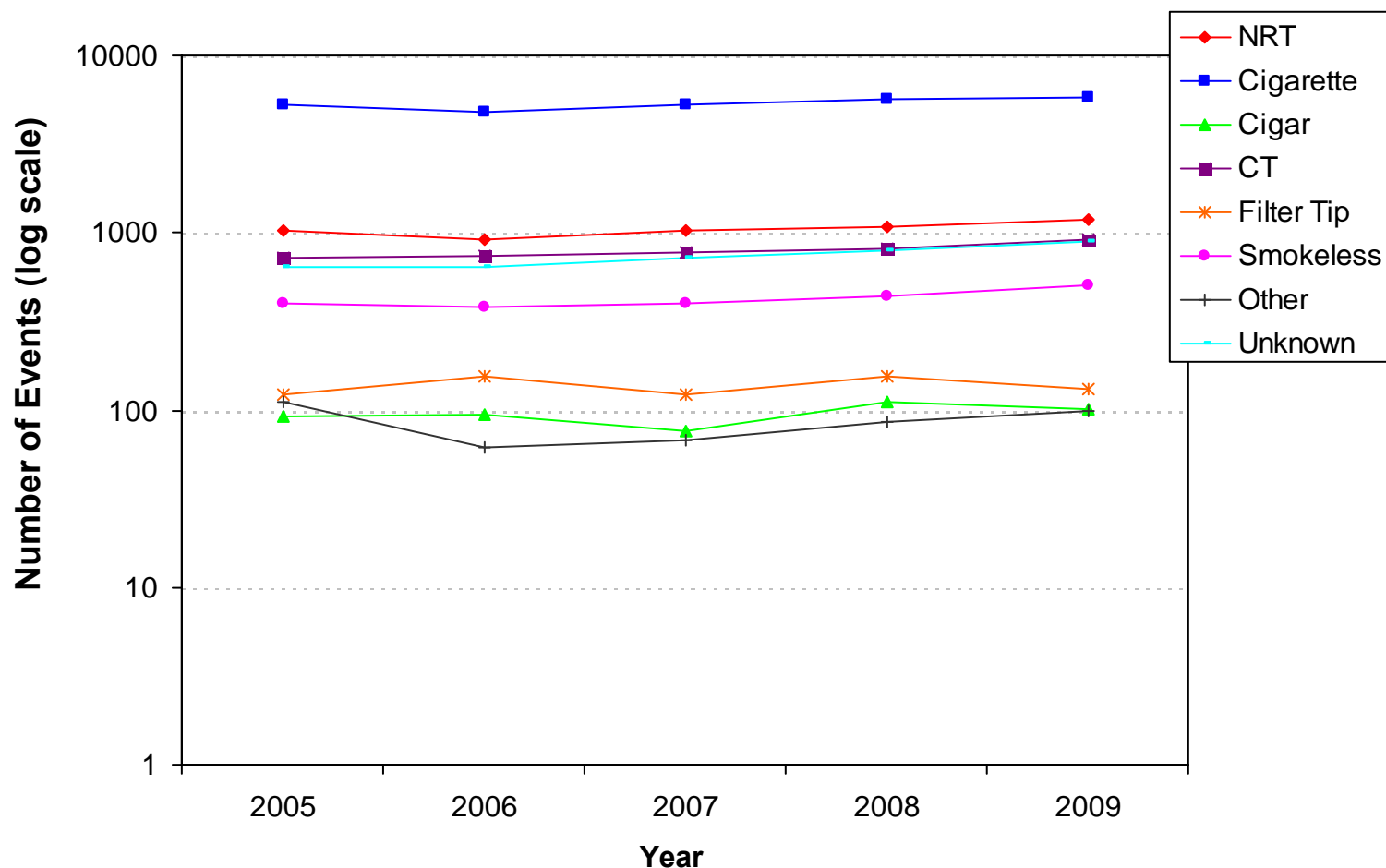
Total number of Nicotine Replacement Therapies Exposure Events by Age (2000 – 2009)

Age group distribution differs from tobacco events, a smaller percentage of NRT reports involve young children compared to tobacco products



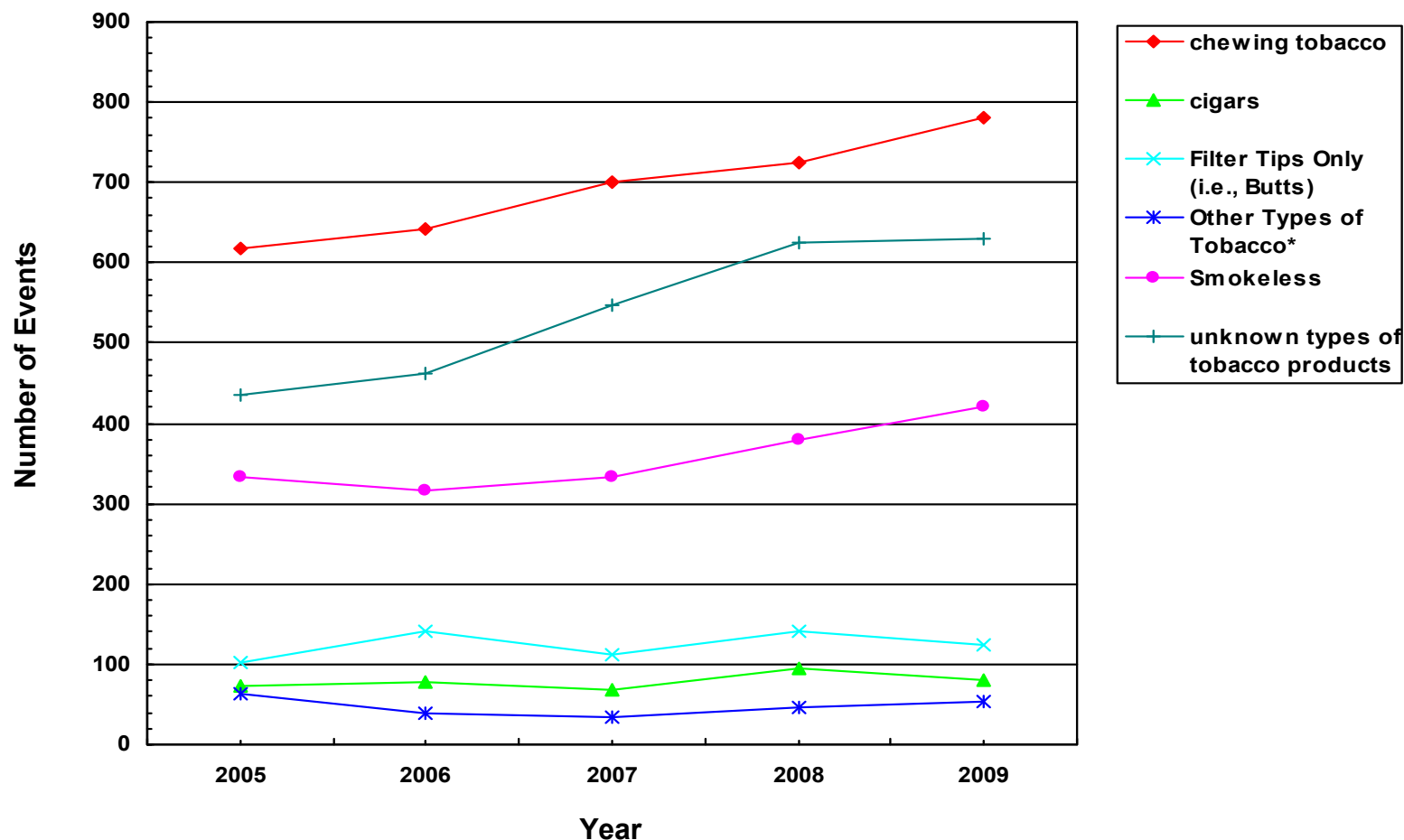
Total number of Exposure Events Associated with Tobacco Products and NRT (2005 – 2009)

Several tobacco subcategories were added in 2005



Frequency of Tobacco Product Exposure Events in Children < 6 Years by Selected Tobacco Product Type, 2005 – 2009

An increase in reports seen for smokeless products over recent years



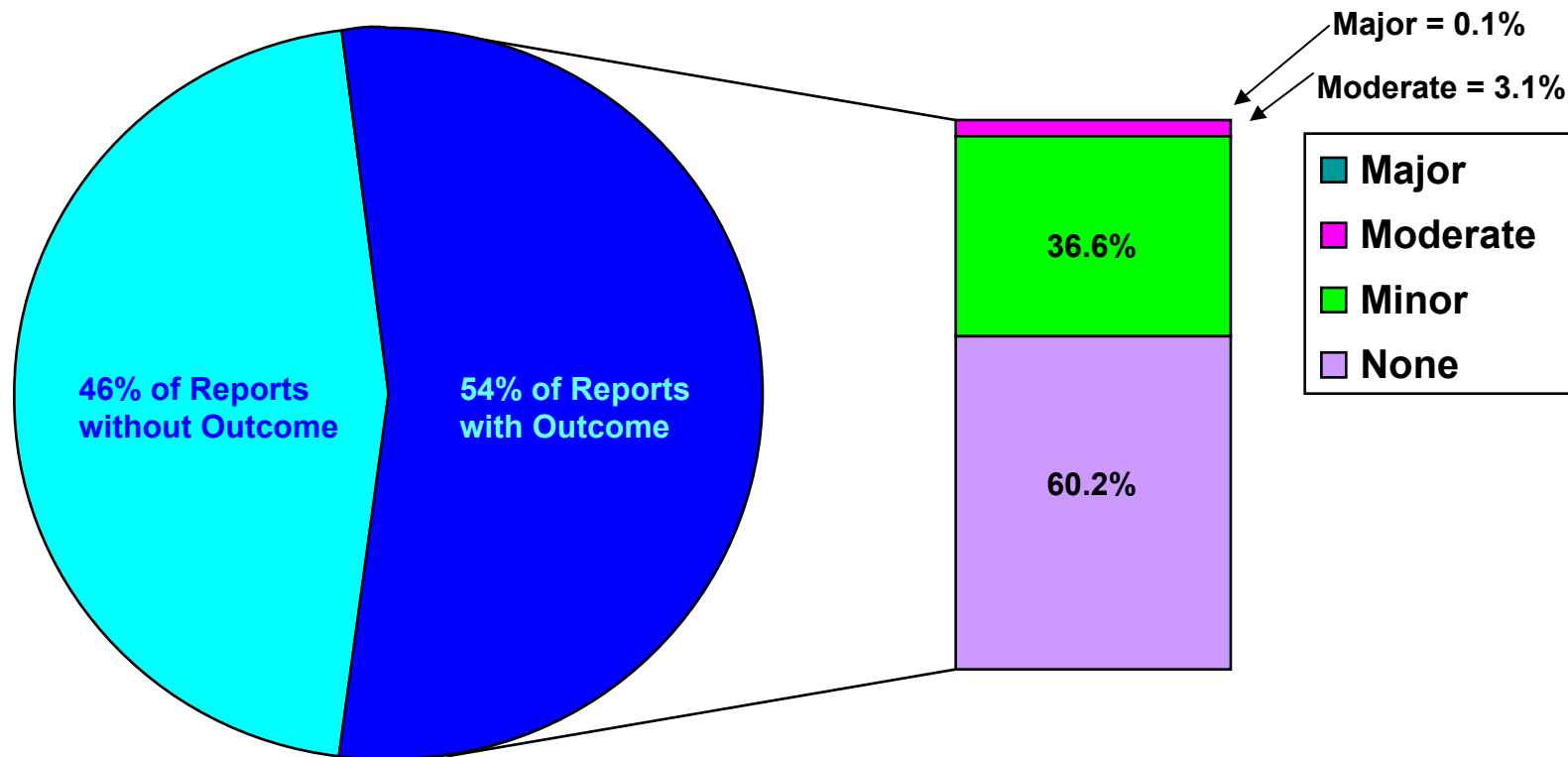
*Included Cigarette smoke condensate, clove cigarettes, green pepper, Marshalls Cubeb cigarettes, etc.

Smokeless Products in Report

- In these AAPCC reports, “Smokeless” includes the following products:
 - Ariva
 - Camel Orbs
 - Camel Sticks
 - Camel Strips
 - Dissolvable Tobacco - not Otherwise Specified
 - Iqmik
 - Snuff (General formulation)
 - Stonewall

Percentage of Reports with/without Severity of Outcomes, 2009

Only half of the reports include information on outcome

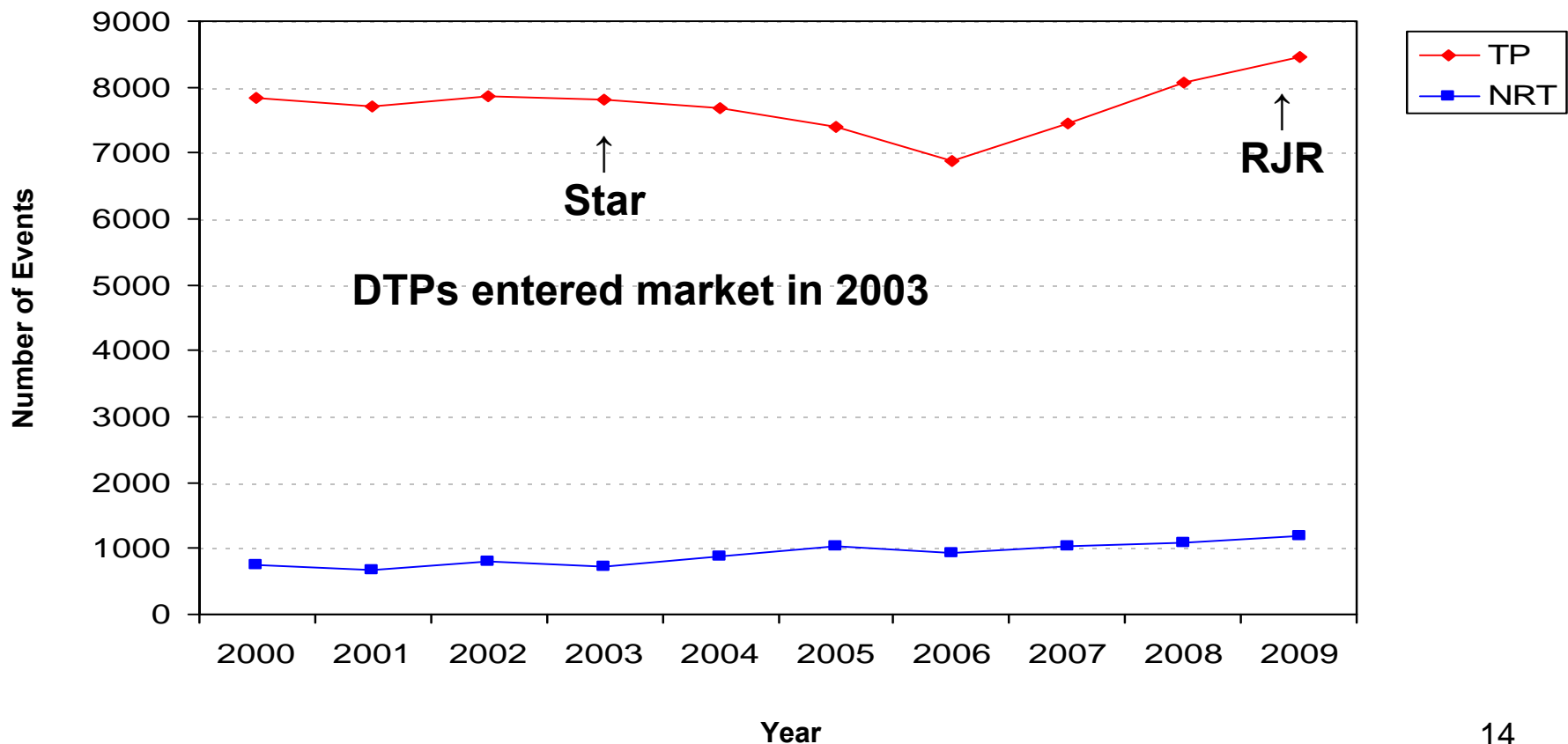


Definitions

- **No effect:** no signs or symptoms as a result of the exposure
- **Minor effect:** some signs or symptoms as a result of the exposure, but were minimally bothersome and generally resolved rapidly with no residual disability or disfigurement. A minor effect is often limited to the skin or mucus membranes.
- **Moderate effect:** signs or symptoms developed that were more pronounced, more prolonged, or more systemic in nature than minor symptoms. Usually, some form of treatment is indicated. Symptoms were not life- threatening, and the patient had no residual disability or disfigurement
- **Major effect:** signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement
- **Death:** The patient died as a result of the exposure or as a direct complication of the exposure.

Total number of Exposure Events Associated with Tobacco Products and NRT, 2000 – 2009

Dissolvable tobacco products are relatively new to the market



Summary

- In the most recently available AAPCC Annual Report (2009) the number for Tobacco Product potential poisoning events is over 8,500 reports with 500+ smokeless reports, which includes DTPs
- 421 of the smokeless events involve young children less than age 6 years
- Recent report of serious accidental ingestion of DTP involving 2 year old child

Summary

- As a regulatory agency with the mission to protect public health, we should work towards reversing this trend and prevent additional cases of potential tobacco poisonings as best possible

Acknowledgement

- Dr. Baoguang Wang – Epidemiology,
Office of Science